# Researching Change in Laboratory Systems

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**Abstract:** Technology, the expansion of managed care, and cuts in Medicare, Medicaid and other government programs to contain the deficit will all force rapid change on laboratory systems. To measure change, it is necessary to use the methods of time series analysis and to specify the dynamics of the process. Whether the terminology used is managed care, reengineering, or fiscal responsibility, the driving force will be money. Two primary indicators of system pressure and efficiency will be the ratios of revenue/cost and FTE/test.

The economic logic of managed care will remove cost-shifting and hence reduce the implicit subsidy of clinical research, so that new sources of dedicated funding must be found in an era of scarcity. The adverse outlook is somewhat mitigated by the fact that capitation is inherently population-based, and potentially more amenable to the methods of public health and health services research than traditional fee-for-service medical practice. Without billable revenues, laboratories will have to engage in cost-benefit research to demonstrate the value of their services. These studies will be similar to the emerging discipline of pharmacoeconomics. Indeed, the pharmacy may be an appropriate role model for the evolution of the laboratory. Pharmacists have shifted from manufacturing, earning money by custom production of pills, salves and solutions, to information services, providing demonstrated value in containing the cost of pharmaceuticals and improving the quality of bedside care. Laboratory research in 2010 is more likely to be collaborative so as to better meet the needs of clinicians, and because industry is apt to become a relatively larger source of funding. A changing structure will necessitate the development of new measures, new administrative data systems, and a new set of protections to defend scientific objectivity.

Change occurs over time. It forces us to use time series methods (rather than cross-sections). In addition to the standard questions (what is the dependent variable, intervening model, independent variables), change forces us to specify a time frame, and to make the model "dynamic" showing how, and how slowly, change occurs. Research is different in time series. The statistics are different, the "N" is different, confidence intervals are different. It becomes very apparent that how the questions are framed may be even more important than data quality in obtaining valid results.

What is our time frame? I would suggest it is on the order of 2 to 20 years; that is, after the next presidential election, but before all the candidates have died or finished writing their memoirs. The reference to politics was made to get a laugh, but also to point out that change occurs because someone wants it to happen, makes it happen, is willing to fight for it. And usually, at the bottom of much of that fighting, is money.

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|---|---|
| √ | Technology |
| √ | Managed Care |
| √ | Funding Cuts |
| ? | Location of Testing |
| ? | Professional Boundaries |
| ø | Demography |
| ø | Economy |

Table 1: Changing Factors: Definite, Maybe or Irrelevant

That is why I, although I am an economist and not a laboratorian, can claim some expertise in addressing this topic. The changes now occurring, whether called managed care, outcomes, re-engineering, or technological revolution, are being driven by money --and someone will have to be willing to put up some money if the necessary research on structural change in the laboratory is to be carried out.

What is changing? Let me briefly list several factors and suggest why some are, some maybe, and some are not relevant (Table 1). Topping my list are three changes that we can confidently predict will affect the laboratory over the next ten years: technology, managed care, and funding cuts. The effects of managed care are the central theme of this presentation. The succeeding sections are given over to building a conceptual model and developing measures to quantify effects. Let me briefly touch upon technology and funding cuts, since they are inextricably involved. How can we be so sure that there will be cuts in medical funding? Examine Figure 1. It is so obvious that U.S. Health care expenditures are out of line, with little evidence of effectiveness for the extra $400 billion spent, that even Congress can see that something is wrong. The deficit reduction is coming out of health care, kicking and screaming for sure, but coming none the less (N.B., "cuts" refer here as they do in most government to reductions in the rate of expenditure increase, although there will be some absolute dollar cuts as well). Technology has been addressed in a number earlier sessions, and there are many here in the audience more qualified to speak about how technological innovation is changing the laboratory. I would however, like to highlight several aspects of particular importance in my analysis--changes in the scale at which laboratory work takes place, reductions in the FTE manpower required per test, and advances in computing and telecommunications which have blurred the boundary between "laboratory testing" and "information services."

Changes in technology lead us to the middle or "maybe" category, where I have chosen two related trends for discussion: location of testing and professional boundaries. The "lab" as a dedicated space within a medical care facility is imploding, hollowed out by the centripetal forces of self testing and regional consolidation. The loss of an identified physical location may exacerbate the challenge to professional identity. Will laboratorians continue to exist when automation reduces the requirements for training in clinical chemistry, but increases the requirements for training in information systems? Will clinical physicians

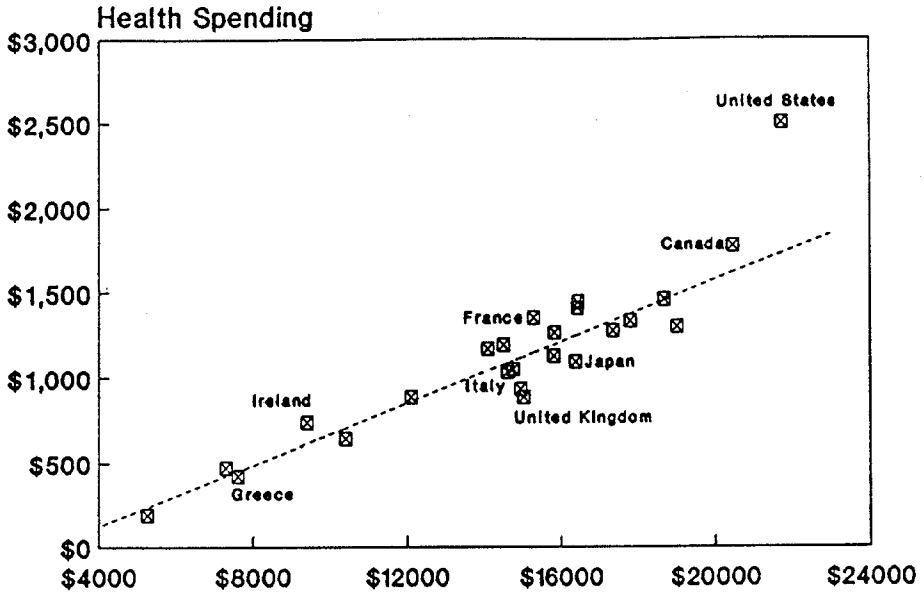


Figure 1. Cross-sectional analysis of 24 countries, 1990.

and insurance companies be users of laboratory services, or will they just take over those functions and any attendant funding?

At the bottom of the list are two factors which are frequently talked about, but which will not have a significant effect: demography and the economy. For all that has been written about the aging of America, the fact is that little aging will take place between now and the year 2020, and furthermore that the dramatic increase in aging around the world has had negligible impact on funding, manpower or other aspects of medical care systems. In brief, aging is a non-issue. The economy is clearly important, but, barring catastrophe, will grow and fluctuate pretty much as it has in the past. It will affect the situations of particular laboratories (sorry, California) but not the system as a whole. There is adequate growth in GDP to fund some expansion and refinement of services, but nowhere near enough money to wash away all of the problems caused by 20 years of excessive health care spending and avoid change.

**Managed Care and Laboratory Billing**

As "Managed Care" expands and mutates, it is sometimes difficult to determine exactly what is meant by the term. There are two elements which are central: "management"--the active intervention of a manager between the payer and the provider in the traditional third party relationship. Sometimes this management role may be internalized by the provider, as it is in a physician gatekeeper, it may be an entirely independent firm that does nothing but manage, as is the case for most commercial HMO's, it may even be a piece of software like "Claimcheck" residing within the computers of a financial system and putting out denials whenever it discovers an undocumented variance. The other fundamental element of managed care is payment by capitation, so many $ per member per month, rather than payment per test or per case. While capitation is still relatively rare for laboratory services, it is

1) Do not pay for cost-shifted overhead.

2) Select patients and providers that are manageable and low cost.

3) Change provider incentives to reduce utilization of limited effectiveness (or where elimination would not be noticed).

-- *NOT* keeping patients healthy (provides social, not corporate, gains).

Table 2: The economic logic of Managed Care

increasing. More importantly, capitation is removing the revenue stream from hospital and outpatient billing. Inpatient laboratory billing grew up as a form of "cost shifting." Early hospitals charged an inclusive per diem that covered nursing, medication, lab, and all other services. The lack of identified payment was problematic for clinical pathology, and in particular, for autopsies (it has always been difficult to claim that a patient benefitted from and should pay for a post-mortem procedure). Billing for laboratory tests was an effective way of subsidizing the necessary scientific services which were important for quality medical care, but not to a specific patient. Indeed, laboratory billing was too good of a way to raise money to be limited to pathology alone, and soon was being used to subsidize all sorts of activities from basic science research to charity and revenue shortfalls in the maternity clinic. Over time, the laboratory became the quintessential cost-shifting engine, transferring money from a place it was easy to get so as help out in places, like emergency rooms, where it was hard to get.

**The logic of managed care is to remove cost shifting**. By paying only what for what the patient needs, and avoiding the cost of autopsies, research, indigent care, etc., the managed care company is able to provide comprehensive services at much lower cost than standard indemnity insurance which has all of the cost-shifted overhead built in. To assess the potential impact of managed care on a department, the single most important measure is the amount of cost-shift overhead it is carrying under fee-for-service, more precisely, the "Revenue/Cost Ratio." Because this ratio is so high in the laboratory, they are especially vulnerable. For years, the excess revenues generated in the laboratory have protected it from cost pressures and management discipline. Those years of easy living not only allowed inefficiencies to creep in, but they also insulated the lab from the demands for accountability which other services faced. Laboratorians have not been good advocates for the value of the information they produce. Until now, they did not have to be. When millions of dollars are coming in and the overflow is being handed out to cover other departments, why work hard at slimming down, or at selling?

Quite simply, the days of easy money are over. Note, however, that we are in a period of transition where the revenues from fee-for-service billing still exceed the revenues from capitation, and will continue to do so until managed care penetration exceeds 75%.

Fee-for-service with high charge/cost ratios is so lucrative that only in a very advanced managed care environment--beyond Minneapolis and San Francisco even, does it make sense to align the laboratory with the long run incentives capitation.

In contrast to fee-for-service, **capitation is inherently population based** There is a clinical logic commensurate with the economic incentives listed above, and one that is much closer to the traditional perspective of public health and health services research than of solo clinical practice. Quality is defined in terms of expected averages, rather than individual procedures or provider credentials.

**Outcomes Research**

Capitation, being based on population averages, is much more amenable to the perspective of outcomes research. Yet contract for outcomes is not possible with current methods. Purchasing by "added life years" or "percentage restored function" may be routine by the end of the next century, but not within the 10 to 20 year time frame examined here. (In this regard it is worth noting that the federal HMO act was passed in 1973, but that managed care is only beginning to impact laboratory practice some 20 years later.) Outcomes research will require a similarly lengthy development period). Another problem with the idea of contracting for outcomes is that differences in the quantity and quality of medical care accounts for only a small percentage (10 to 20%) of the variation in health status. The acute medical model of discrete illness, with a well defined treatable diagnosis whose management can be made more efficient through refinement of protocols or "clinical pathways," may be applicable to as much as 80% of the population, but to only 20% of the cost. Alzheimer's disease, AIDS, crack babies, social pathology, mental illness and other "exceptions" take the great majority of the dollars. These social disorders and the massive cross-subsidy of the disabled ill by wage earners may be the issue which blunts (or sharpens) the penetration of managed care. In the year 2005, the dominant revenue streams will come from **contracting by capitation, but not by outcomes**

**The Pharmacy as A Model for Laboratory System Change**

Two challenges which threaten the viability of laboratories are 1)automation, which may reduce the numbers and presence of the profession below a sustainable level, and 2) an inability to defend the value of their work in an environment where tests generate no revenues. The pharmacy, and the evolution of the pharmacist, may provide a model for successful adaptation to similar threats. Once upon a time, pharmacists manufactured pills, ointments and elixirs. Their value added was embodied in the process of production. Prepackaging, automated quality control and other innovations drastically reduced the value of custom individual on-site production. The role of the pharmacist has become that of information manager and clinical coordinator. Rather than defending the pill, they have become instruments for more effective control of pharmaceutical costs. Laboratorians must make a similar leap if they are to have a sizable role in the medical system of the 21st century. Attempting to hold on to traditional roles will mean that those functions are defaulted to physicians, nurses, administrators and other professionals in the health care system.

**How to Conduct the Research**

The end of cost-shifting means that most research, which has been heavily subsidized by patient care revenues, must obtain dedicated funding. It will may no longer be possible to enroll patients in clinical trials without paying for them. Unfortunately, the only ones likely to step forward with money for research are those firms that stand to benefit from the results. The need to demonstrate the value of laboratory services will be a tremendous boon to outcome studies, but the companies supporting those studies inevitably look on them as a part of their marketing effort. There will be a need to develop collaborative models for research which protect the objectivity of the process. Capitation will force laboratories to develop population based measures. The information system demands will be such that each test result, even from a hand-held analyzer, must be placed in a universal standard format, with a unique patient identifier up front. As systems become more integrated, the "hospital" and "clinic" will disappear as meaningful entities, so that the only appropriate denominator will be the individual (or collectively, a specified population).

**What to measure**

It will be necessary to understand the changes in the industry and how it is being transformed. It will often not be possible or worthwhile to investigate quantitatively the performance of each laboratory. Rather, research must focus on developing **structural indicators**, simple check-off questions that can be answered about organizational characteristics of the lab that are related to efficiency and quality (e.g., is the lab able to report rates of infection for defined populations? has the lab participated in developing of 2 or more clinical pathways or cost-benefit studies in the past year? to whom does the director of the laboratory report? and how well is their daily communication (not reporting) between laboratorians and clinicians, with evidence of changes in clinical practice, etc.?)